



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 123

[Docket No. FDA-2013-D-0269]

Draft Guidance for Industry on Purchasing Reef Fish Species Associated With the Hazard of Ciguatera Fish Poisoning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled “Guidance for Industry: Purchasing Reef Fish Species Associated With the Hazard of Ciguatera Fish Poisoning.” The draft guidance, when finalized, will advise primary seafood processors who purchase reef fish how to minimize the risk of ciguatera fish poisoning (CFP) from fish that they distribute. The draft guidance is intended to help protect the public health by reducing the risk of CFP.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852. Submit written requests for single copies of the draft guidance to Division of Seafood Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Karen Swajian,
Division of Seafood Safety,
Center for Food Safety and Applied Nutrition (HFS-325),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
240-402-2300.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft guidance entitled “Guidance for Industry: Purchasing Reef Fish Species Associated With the Hazard of Ciguatera Fish Poisoning.” The draft guidance is intended for primary seafood processors who purchase reef fish such as grouper, amberjack, snapper, lionfish, king mackerel, and barracuda. The draft guidance recommends that primary seafood processors take measures to minimize the risk of CFP from fish that they distribute. This draft guidance is an update to and complements information from the guidance document entitled “Fish and Fishery Products Hazards and Controls Guidance” (the Guide) (Ref. 1), which helps the seafood processing industry develop seafood Hazard Analysis

and Critical Control Point programs. The Guide identifies food safety hazards, including CFP, which are associated with fish and fishery products, and provides examples of recommended preventive measures to minimize the likelihood of the hazard's occurrence. Table 3-2 in the Guide provides a list of fish species currently associated with CFP. The draft guidance adds to the list of reef fish species associated with CFP.

The draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site to find the most current version of the draft guidance.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.)

1. Food and Drug Administration, “Fish and Fishery Products Hazards and Controls Guidance,” April 28, 2011, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>.

Dated: March 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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